

**PSJ14 Janssen Opp Exh 62 – JAN-MS-02983578**

**From:** Dempsey, Michele [GPSUS]  
**To:** Sniscak, Debbie [GPSUS]  
**Sent:** 1/23/2018 4:18:34 PM  
**Subject:** recommendations

Here you go.

Start resolving the issue of possibly not applying the SOM order quantity assessment algorithm (SOM algorithm) to all customer orders for Schedule III and IV controlled substances which are received via electronic data interchange (EDI) throughout the day and night. The SOM algorithm is run against all existing controlled substances orders each day at 3:45 PM. Any orders that are received by J&J customer service via EDI after that time may be shipped to a customer the following day without being subjected to the SOM algorithm unless the EDI orders are checked the next morning to ensure the SOM algorithm has been applied

Start modifying the existing SOM algorithm and/or adding algorithms to include additional evaluation criteria for each specific DEA basic class of controlled substance handled by J&J (e.g., fentanyl, methylphenidate, tramadol). Consider a base unit of measurement, such as grams of active ingredient for the SOM algorithm(s). Consider separating J&J customers into two or more groups and perform different analyses of orders for these different groups (e.g., largest three wholesalers in one group; smaller wholesalers in another group). Consider evaluating customer orders for specific DEA basic classes of substances against similar size and geographically-placed customers, and perform national, regional, state and perhaps three-digit zip code comparisons among like size customers

Stop using the current single criterion algorithm which selects and holds orders from customers when the quantity of an order is greater than three times (300 percent) the customer's average weekly order, based on a rolling twelve (12) month ordering history from that customer. This algorithm only measures quantity and does not consider frequency or a pattern of ordering by the same customer. The algorithm compares a customer's order quantity against only that customer's average annual purchases. The algorithm would not detect multiple customer orders during a given week; it would not detect orders which consist of gradual quantity increases of a controlled substance over time; it would not detect a new customer's orders for controlled substances which initially commence with larger than normal quantities and remain at a constant level. This algorithm does not distinguish between controlled substances, geographic areas, or similar size customers (e.g., similar size wholesaler).

If a threshold is established for a given customer or product and it proves not to be effective in accomplishing the intended purpose, it can and should be revised. When long term, well established customers' ordering patterns, frequencies, and quantities are known, thresholds can be set accordingly. It may be instructive to divide customers into defined groupings and intentionally establish thresholds at strict levels for purposes of establishing a baseline of ordering activity. It may also be effective to have more than one calculation depending on the drug product or the type of customer. These calculations can be built into SAP without need for external systems or connections. In some cases, it will be necessary for certain orders to be subjected to more extensive investigation. It is essential that the individuals and/or group (Controlled Substances Compliance) responsible for detecting suspicious orders be part of the development/modification of the calculation(s) and setting of a threshold or multiple thresholds;

Start enhancing the JOM SOM program; and be more assertive in the implementation of the JOM SOM in the context of enhancing customer relationships

<ul style="list-style-type: none"> <li>• Take past order examples and evaluate their circumstances, order patterns and activity against revised algorithm(s) to determine discrepancies or adjustments needed;</li> </ul>
<ul style="list-style-type: none"> <li>• Increase SOM related data collection and analysis. Utilize IntegriChain data, data from Value Centric's Value Trak 852 and 867 EDI programs to evaluate and/or verify customer inventory levels and activities</li> </ul>
<ul style="list-style-type: none"> <li>• Evaluate the usefulness of IMS data, particularly for planned future retail activities;</li> </ul>
<ul style="list-style-type: none"> <li>• Consider including ARCOS historical purchase data to assist in establishing customer trends;</li> </ul>
<ul style="list-style-type: none"> <li>• Determine the feasibility of using State Prescription Drug Monitoring Program (PDMP) data (if available);</li> </ul>
<ul style="list-style-type: none"> <li>• Evaluate chargeback data and information in J&amp;J's possession, and determine if any of the data or information is of value to the goals and objectives of the JOM SOM program. If the chargeback data and information are useful, then consider monthly or quarterly, completing runs of all chargeback data by distributor by drug class by pharmacy (with quantities) and compare with a run of all pharmacies controlled substance purchases without regard to the distributor that submitted the chargeback. Consider using chargeback data to assist in evaluating regional distribution trends for J&amp;J controlled substance products. If appropriate, consider eliminating chargebacks for select products and/or customers;</li> </ul>
<ul style="list-style-type: none"> <li>• Continue the SOM team's interaction with internal stakeholders, e.g., Brand Teams on pharmacy communications, SOM education and compliance; seek greater data and information from retail chains (i.e. basis for your distributor's order) with detailed breakdown by store number or another identifier</li> </ul>
<p>During the SOM Workshop conducted on December 13, 2017, there was discussion of the possibility of establishing an upfront assessment of all customer controlled substance orders by customer size, and quantity and drug class ordered to determine a customer specific set of values or criteria that would enable an expeditious initial decision on the order; and then follow this initial decision with a more detailed analysis and evaluation of the order and customer retrospectively. The objective would be to have an initial "atypical" order determination at the time the order is created. This was an excellent discussion and it is recommended that the issue be pursued</p>

*Michele Dempsey*



Director, Controlled Substance Compliance  
302 345-4621 (Cell)  
[mdempse3@its.jnj.com](mailto:mdempse3@its.jnj.com)

Confidentiality Notice: This e-mail transmission may contain confidential or legally privileged information that is intended only for the individual or entity named in the e-mail address. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution, or reliance upon the contents of this e-mail is strictly prohibited. If you have received this e-mail transmission in error, please reply to the sender, so that Johnson & Johnson can arrange for proper delivery, and then please delete the message from your inbox. Thank you.